

AO 120 (Rev. 08/10)

| | |
|---|---|
| TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 | REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK |
|---|---|

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court _____ for the District of Delaware _____ on the following

☐ Trademarks or ☒ Patents. (☐ the patent action involves 35 U.S.C. § 292.);

| | | |
|--|--------------------------------|--|
| DOCKET NO. 16-917 | DATE FILED 10/7/2016 | U.S. DISTRICT COURT for the District of Delaware |
| PLAINTIFF FOREST LABORATORIES, LLC, et al. | | DEFENDANT AMERIGEN PHARMACEUTICALS, INC., et al. |
| PATENT OR TRADEMARK NO. | DATE OF PATENT OR TRADEMARK | HOLDER OF PATENT OR TRADEMARK |
| 1 8,039,009 B2 | 10/18/2011 | Forest Laboratories Holdings Ltd. |
| 2 8,058,291 B2 | 11/15/2011 | Adamas Pharmaceuticals, Inc. |
| 3 8,168,209 B2 | 5/1/2012 | Adamas Pharmaceuticals, Inc. |
| 4 8,173,708 B2 | 5/8/2012 | Adamas Pharmaceuticals, Inc. |
| 5 8,283,379 B2 | 10/9/2012 | Adamas Pharmaceuticals, Inc. |

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

| | | | |
|----------------------------|---|-------------------------------|--|
| DATE INCLUDED | INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading | | |
| PATENT OR TRADEMARK NO. | DATE OF PATENT OR TRADEMARK | HOLDER OF PATENT OR TRADEMARK | |
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |

In the above—entitled case, the following decision has been rendered or judgement issued:

| |
|---|
| DECISION/JUDGEMENT Stipulation of Dismissal |
|---|

| | | |
|--------------------------------|-------------------|---------------------------|
| CLERK John A. Cerino | (BY) DEPUTY CLERK | DATE 10-28-2016 |
|--------------------------------|-------------------|---------------------------|

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

ADDENDUM TO AO 120 (ADDITIONAL PATENTS)

| | | | |
|---|----------------------------|--------------------------------|---|
| DOCKET NO. | | DATE FILED 10/7/2016 | U.S. DISTRICT COURT for the District of Delaware |
| PLAINTIFF FOREST LABORATORIES, LLC, et al. | | | DEFENDANT AMERIGEN PHARMACEUTICALS, INC., et al. |
| | PATENT OR TRADEMARK NO. | DATE OF PATENT OR TRADEMARK | HOLDER OF PATENT OR TRADEMARK |
| 6 | 8,293,794 B2 | 10/23/2012 | Adamas Pharmaceuticals, Inc. |
| 7 | 8,329,752 B2 | 12/11/2012 | Adamas Pharmaceuticals, Inc. |
| 8 | 8,338,485 B2 | 12/25/2012 | Adamas Pharmaceuticals, Inc. |
| 9 | 8,338,486 B2 | 12/25/2012 | Adamas Pharmaceuticals, Inc. |
| 10 | 8,362,085 B2 | 1/29/2013 | Adamas Pharmaceuticals, Inc. |
| 11 | 8,580,858 B2 | 11/12/2013 | Adamas Pharmaceuticals, Inc. |
| 12 | 8,598,233 B2 | 12/3/2013 | Adamas Pharmaceuticals, Inc. |

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|-----------------------|
| FOREST LABORATORIES, LLC, <i>et al.</i> , |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | C.A. No. 16-917 (LPS) |
| |) | |
| AMERIGEN PHARMACEUTICALS, INC., |) | |
| <i>et al.</i> , |) | |
| |) | |
| Defendants. |) | |

STIPULATION AND DISMISSAL ORDER

The Court, upon the consent and request of Plaintiffs Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.), Forest Laboratories Holdings, Ltd., Allergan USA, Inc. and Adamas Pharmaceuticals, Inc. (collectively, "Plaintiffs") and Defendants Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. (collectively, "Amerigen"), hereby acknowledges the following Stipulation and issues the following Dismissal Order in this action (the "Action").

STIPULATION

1. This Stipulation and all terms and admissions herein apply solely to the 21 mg/10 mg and 7 mg/10 mg strength generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products described in Amerigen Pharmaceuticals Ltd.'s Abbreviated New Drug Application ("ANDA") 208237 and that are the subject of the Action, and do not apply, and shall not be used by Plaintiffs with respect, to any other strengths or products described in Amerigen Pharmaceuticals Ltd.'s ANDA 208237.

2. This Court has subject matter jurisdiction over this Action and personal jurisdiction over Plaintiffs and Amerigen for the limited purposes of the Action. Venue is proper in this Court as to Plaintiffs and Amerigen solely for the limited purposes of the Action.

3. In the Action, Plaintiffs have asserted claims against Amerigen for infringement of U.S. Patent Nos. 8,039,009 ("the '009 Patent"), 8,058,291 ("the '291 Patent"), 8,168,209 ("the '209 Patent"), 8,173,708 ("the '708 Patent"), 8,283,379 ("the '379 Patent"), 8,293,794 ("the '794 Patent"), 8,329,752 ("the '752 Patent"), 8,338,485 ("the '485 Patent"), 8,338,486 ("the '486 Patent"), 8,362,085 ("the '085 Patent"), 8,580,858 ("the '858 Patent"), and 8,598,233 ("the '233 Patent") in connection with Amerigen Pharmaceuticals Ltd.'s submission of ANDA 208237 directed to generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products, 21 mg/10 mg and 7 mg/10 mg, to the U.S. Food and Drug Administration ("FDA").

4. In response to Plaintiffs' claims of patent infringement, Amerigen has alleged certain defenses and counterclaims, including that the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, and the '233 Patent are invalid, unenforceable, and/or not infringed by the filing of Amerigen Pharmaceuticals Ltd.'s ANDA 208237 with the FDA for generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products, 21 mg/10 mg and 7 mg/10 mg, and/or any making, using, selling, or offering to sell within the United States, or importing into the United States, of the generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products, 21 mg/10 mg and 7 mg/10 mg, described by ANDA 208237. To date, no decision has been obtained from this Court in the Action regarding Plaintiffs' claims of infringement against Amerigen, or Amerigen's defenses and counterclaims.

5. Amerigen admits that the submission of ANDA 208237 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, and/or

sale of the generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products, 21 mg/10 mg and 7 mg/10 mg, within the United States before the expiration of the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, and the '233 Patent was a technical act of infringement of each of those patents under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to Amerigen's defenses and counterclaims in the Action that the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, and the '233 Patent are invalid, unenforceable, and/or not infringed by any making, using, selling, or offering to sell within the United States, or importing into the United States, of the 21 mg/10 mg and 7 mg/10 mg strength generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products described by ANDA 208237. This admission is further without prejudice to any claim, defense, or counterclaim in any possible future action between Amerigen and any of the Plaintiffs regarding the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, the '233 Patent, and/or a generic memantine hydrochloride extended-release and donepezil hydrochloride product other than any 21 mg/10 mg and 7 mg/10 mg strength generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products, including any other strengths or products described by ANDA 208237.

6. Both parties agree that all other claims, defenses, and counterclaims set forth in Plaintiffs' and Amerigen's pleadings against each other in the Action, including the allegations and averments contained therein, should be dismissed, without prejudice.

DISMISSAL ORDER

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Plaintiffs and Amerigen, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. This Dismissal Order and all terms and admissions herein apply solely to the 21 mg/10 mg and 7 mg/10 mg strength generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products described in Amerigen Pharmaceuticals Ltd.'s ANDA 208237 and that are the subject of the Action, and do not apply, and shall not be used by Plaintiffs with respect, to any other strengths or products described in Amerigen Pharmaceuticals Ltd.'s ANDA 208237.

2. The filing of ANDA 208237 for the 21 mg/10 mg and 7 mg/10 mg strength generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products was a technical act of infringement of the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, and the '233 Patent under 35 U.S.C. § 271(e)(2)(A). No decision in the Action has been obtained by either party regarding the validity of the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, and the '233 Patent, the enforceability of those patents, and/or whether any making, using, selling, or offering to sell within the United States, or importing into the United States, of the 21 mg/10 mg and 7 mg/10 mg strength generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products described by ANDA 208237 would infringe those patents.

3. All claims, defenses, and counterclaims set forth in Plaintiffs' and Amerigen's pleadings against each other in the Action, including the allegations and averments contained therein, are hereby dismissed, without prejudice.

4. Except as and to the extent authorized by Plaintiffs or permitted pursuant to an applicable license agreement, Amerigen, its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them who receive actual notice of this Dismissal Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, only the 21 mg/10 mg and 7 mg/10 mg strength generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products described by ANDA 208237, during the life of the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, and the '233 Patent, including any extensions and pediatric exclusivities, unless all of the claims of the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, and the '233 Patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court.

5. Plaintiffs and Amerigen each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Dismissal Order.

6. This Court retains jurisdiction over Plaintiffs and Amerigen for purposes of enforcing this Stipulation And Dismissal Order.

7. This Stipulation And Dismissal Order shall finally resolve the Action.

8. This Stipulation And Dismissal Order is without prejudice to any claim, defense, or counterclaim in any possible future action between Amerigen and any of the Plaintiffs regarding the '009 Patent, the '291 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '794 Patent, the '752 Patent, the '485 Patent, the '486 Patent, the '085 Patent, the '858 Patent, and/or the '233 Patent and a generic product other than any 21 mg/10 mg and 7 mg/10 mg generic memantine hydrochloride extended-release and donepezil hydrochloride capsule products including those described by ANDA 208237.

9. The Clerk of the Court is directed to enter this Stipulation And Dismissal Order forthwith.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

RICHARDS, LAYTON & FINGER, P.A.

/s/ Maryellen Noreika

/s/ Kelly E. Farnan

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Kelly E. Farnan (#4395)
Selena E. Molina (#5936)
Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700
farnan@rlf.com
molina@rlf.com

Attorneys for Plaintiffs

*Attorneys for Defendants Amerigen
Pharmaceuticals, Inc. and Amerigen
Pharmaceuticals Ltd.*

SO ORDERED this 25th day of October 2016.


THE HONORABLE LEONARD P. STARK,
CHIEF, UNITED STATES DISTRICT JUDGE